IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TRIS PHARMA,INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
ACTAVIS LABORATORIES FL, INC., ANDRX CORPORATION, ACTAVIS, INC., and ACTAVIS PHARMA, INC.,	)	
	)	
Defendants.	)	

COMPLAINT

1. Tris Pharma, Inc. ("Tris" or "Plaintiff"), for its Complaint against Actavis Laboratories FL, Inc. ("Actavis FL"), Andrx Corporation ("Andrx"), Actavis, Inc., and Actavis Pharma, Inc. ("Actavis Pharma") (collectively "Actavis" or "Defendants"), alleges as follows:

NATURE OF THE ACTION

2. This is an action for patent infringement arising under the Patent and Food and Drug laws of the United States, Titles 35 and 21, United States Code.

3. On information and belief, Defendants have been and are engaging in activities directed toward infringement of United States Patent No. 8,465,765 ("the '765 patent"), United States Patent No. 8,563,033 ("the '033 patent"), and United States Patent No. 8,778,390 ("the '390 patent"), by, *inter alia*, submitting an abbreviated new drug application designated ANDA No. 206049 seeking FDA approval to manufacture and commercially market their proposed product called "Methylphenidate HCl Extended Release Oral Suspension, CII" (hereinafter referred to as "Actavis's ANDA Product") containing the active ingredient methylphenidate HCl.

4. In a letter dated September 3, 2014, entitled "Notification of Certification for U.S. Patent Nos. 8,062,667; 8,287,903; 8,465,765; 8,563,033 and 8,778,390 Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act" (hereinafter referred to as the "September 3 Notice Letter"), Actavis FL notified Tris that it had filed ANDA No. 206049 and that it intends to manufacture and commercially market Actavis's ANDA Product (a generic version of Quillivant XR®) before expiration of the '765, '033, and '390 patents.

THE PARTIES

5. Plaintiff Tris is a company organized and existing under the laws of the State of New Jersey, having its principal place of business at 2033 Route 130, Suite D, Monmouth Junction, NJ 08852.

6. Tris is engaged in the business of research, development, manufacture, and sale of pharmaceutical products for sale throughout the U.S.

7. On information and belief, defendant Actavis FL is a corporation organized and existing under the laws of the State of Florida, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. On information and belief, Actavis FL is a wholly-owned subsidiary of Andrx.

8. On information and belief, Actavis FL is in the business of manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of Delaware and throughout the United States. On information and belief, Actavis FL is registered with the Delaware Board of Pharmacy, pursuant to 24 Del. C. § 2540, as a licensed "Pharmacy-Wholesale" (License No. A4-0001263) and "Distributor/Manufacturer CSR" (License No. DS0499).

9. On information and belief, defendant Andrx is a corporation organized under the laws of the State of Delaware, having designated its registered agent as The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801. On information and belief, Andrx is a wholly-owned subsidiary of Actavis, Inc.

10. On information and belief, defendant Actavis Pharma is a corporation organized and existing under the laws of the State of Delaware, having a place of business at Morris Corporate Center III, 400 Interspace Parkway, Parsippany, NJ 07054. On information and belief, Actavis Pharma is a wholly-owned subsidiary of Actavis, Inc.

11. On information and belief, Actavis Pharma is in the business of, among other things, marketing and distributing pharmaceutical products in the State of Delaware and throughout the United States, including those that are manufactured by Actavis FL. On information and belief, Actavis Pharma is registered with the Delaware Board of Pharmacy, pursuant to 24 Del. C. § 2540, as a licensed "Pharmacy-Wholesale" (License Nos. A4-0000627, A4-0000683 and A4-0001998) and "Distributor/Manufacturer CSR" (License Nos. DS0503 and DS0319).

12. On information and belief, defendant Actavis, Inc. is a corporation organized and existing under the laws of the State of Nevada, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

13. On information and belief, Actavis, Inc. is in the business of, among other things, marketing and distributing pharmaceutical products in the State of Delaware and throughout the United States, including those that are manufactured by Actavis FL.

JURISDICTION AND VENUE

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, and venue is proper pursuant to 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

15. This Court has personal jurisdiction over Defendants because they have purposefully availed themselves of the privilege of selling their pharmaceutical products in the State of Delaware and, therefore, can reasonably expect to be subject to jurisdiction in the Delaware courts. Among other things, on information and belief, Defendants conduct marketing and sales activities in the State of Delaware, including, but not limited to, the distribution, marketing, and sales of pharmaceutical products to Delaware residents that are continuous and systematic.

16. On information and belief, Defendants share common officers and directors and are agents of each other, or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products throughout the United States, including in the State of Delaware.

17. Defendants have previously submitted to the jurisdiction of the United States District Court for the District of Delaware at least in *Duchesnay Inc. et al. v. Actavis Laboratories FL, Inc. et al.*, No. 14-912-SLR, D.I. 9 (D.Del. Sept. 14, 2014); *Cephalon, Inc. v. Actavis Laboratories FL, Inc. et al.*, No. 14-776-SLR-SRF, D.I. 16 (D.Del. July 25, 2014); and *Acorda Therapeutics, Inc. v. Actavis Laboratories FL, Inc. et al.*, No. 14-882-LPS, D.I. 14 (D.Del. Aug. 22, 2014).

18. On information and belief, Actavis FL, Andrx and Actavis Pharma operate as an integrated business ultimately owned and controlled by Actavis, Inc.

19. On information and belief, this Court has personal jurisdiction over Actavis FL by virtue of, *inter alia*: (1) its presence in Delaware, including through Actavis Pharma; (2) its course of conduct that is designed to cause the sale of its products in Delaware; (3) its licenses to distribute/manufacture and pharmacy-wholesale license in Delaware; and (4) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

20. On information and belief, this Court has personal jurisdiction over Actavis Pharma by virtue of, *inter alia*: (1) its presence in Delaware, including its incorporation in Delaware; (2) its course of conduct that is designed to cause the sale of its products in Delaware; (3) its licenses to distribute/manufacture and pharmacy-wholesale license in Delaware; and (4) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

21. On information and belief, this Court has personal jurisdiction over Andrx by virtue of, *inter alia*: (1) its presence in Delaware, including its incorporation in Delaware; (2) its course of conduct that is designed to cause the sale of its products in Delaware; and (3) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

22. On information and belief, this Court has personal jurisdiction over Actavis, Inc. by virtue of, *inter alia*: (1) its presence in Delaware, including through Actavis Pharma; (2) its course of conduct that is designed to cause the sale of its products in Delaware; and (3) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

FIRST CLAIM FOR RELIEF: '765 PATENT

23. Tris realleges paragraphs 1-22 above as if set forth specifically here.

24. The '765 patent (copy attached as Exhibit A), entitled "Orally Effective Methylphenidate Extended Release Powder And Aqueous Suspension Product," was issued on June 18, 2013 to Tris, upon assignment from the inventors Ketan Mehta, Yu-Hsing Tu and Ashok Perumal. The '765 patent claims, *inter alia*, a methylphenidate aqueous extended release oral suspension, and methods of treatment of a patient with such a suspension.

25. Plaintiff Tris has been and still is the owner of the '765 patent. The '765 patent will expire on February 15, 2031.

26. In the September 3 Notice Letter, Actavis FL notified Tris that its ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the '765 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '765 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

27. On information and belief, at the time the September 3 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 26 above.

28. Defendants acknowledged and represented that the September 3 Notice Letter meets the statutory and regulatory requirements referred to in paragraph 26, above.

29. The September 3 Notice Letter alleges that Actavis's ANDA Product does not infringe claims 4, 12, and 27 of the '765 Patent. Actavis alleges that it does not infringe claim 4 of the '765 Patent because Actavis's ANDA Product "will not employ a barrier coating comprising a poly(ethyl acrylate-co-methyl methacrylate-co-trimethylammonoethyl methacrylate chloride) polymer system." Actavis also alleges that it does not infringe claim 12 of the '765 patent because Actavis's ANDA Product "will not employ polyvinylacetate as a matrix-forming component." Actavis also alleges that it does not infringe claim 27 of the '765 patent because Actavis's ANDA Product "will not be in a tablet or capsule form."

30. The September 3 Notice Letter provides no other explanation or allegation why Actavis's ANDA Product does not infringe any claim of the '765 patent.

31. Actavis failed to address any limitations relating to claims 1-3, 5-11, 13-26, and 28-30 of the '765 patent as required by statute and regulation (see paragraph 26, above), thus acknowledging that its ANDA Product meets the all the limitations of these claims.

32. Actavis infringed one or more of the '765 patent claims under 35 U.S.C. § 271(e)(2) by filing its ANDA and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent prior to the expiration of the '765 patent.

33. Unless enjoined by this Court, Actavis will directly infringe the '765 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by

making, using, offering to sell, importing, and/or selling Actavis's ANDA Product in the United States in violation of 35 U.S.C. §§ 271(a).

34. Unless enjoined by this Court, Actavis will induce the infringement of the '765 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Actavis's ANDA Product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Tris's rights under the '765 patent and in violation of 35 U.S.C. § 271(b).

35. Unless enjoined by this Court, Actavis will induce the infringement of the '765 patent by actively and intentionally encouraging, through its label, the infringing use of Actavis's ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Tris's rights under the '765 patent and in violation of 35 U.S.C. § 271(b).

36. Unless enjoined by this Court, Actavis will contribute to the infringement of the '765 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of Actavis's ANDA Product or equipment for the manufacture of Actavis's ANDA Product to others, including manufacturers and distributors, where such materials and apparatuses are not staple articles or commodities of commerce suitable for non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of Actavis's ANDA Product in contravention of Tris's rights under the '765 patent in violation of 35 U.S.C. § 271(c).

37. Tris will be substantially and irreparably damaged and harmed if Actavis's infringement of the '765 patent is not enjoined.

38. Tris does not have an adequate remedy at law for Actavis's infringement of the '765 patent.

39. In the September 3 Notice Letter, Actavis has presented no reasonable or good faith position that the '765 patent claims are invalid.

40. This case is an exceptional one, and Tris is entitled to an award of reasonable attorney's fees under 35 U.S.C. § 285.

SECOND CLAIM FOR RELIEF: '033 PATENT

41. Tris realleges paragraphs 1-40 above as if set forth specifically here.

42. The '033 patent (copy attached as Exhibit B), entitled "Orally Effective Methylphenidate Extended Release Powder And Aqueous Suspension Product," was issued on October 22, 2013 to Tris, upon assignment from the inventors Ketan Mehta, Yu-Hsing Tu and Ashok Perumal. The '033 patent claims, *inter alia*, a methylphenidate aqueous extended release oral suspension, and methods of treatment of a patient with such a suspension.

43. Plaintiff Tris has been and still is the owner of the '033 patent. The '033 patent will expire on February 15, 2031.

44. In the September 3 Notice Letter, Actavis FL notified Tris that its ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the '033 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '033 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R.

§ 314.95(c)(6)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

45. On information and belief, at the time the September 3 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 44 above.

46. Defendants acknowledged and represented that the September 3 Notice Letter meets the statutory and regulatory requirements referred to in paragraph 44, above.

47. The September 3 Notice Letter provides no explanation or allegation why Actavis's ANDA Product does not infringe any claim of the '033 patent.

48. By failing to address non-infringement of any claims of the '033 patent, Actavis acknowledged that its ANDA Product meets the all the limitations of these claims.

49. Actavis infringed the '033 patent under 35 U.S.C. § 271(e)(2) by filing its ANDA and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent prior to the expiration of the '033 patent.

50. Unless enjoined by this Court, Actavis will directly infringe the '033 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Actavis's ANDA Product in the United States in violation of 35 U.S.C. §§ 271(a).

51. Unless enjoined by this Court, Actavis will induce the infringement of the '033 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Actavis's ANDA Product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Tris's rights under the '033 patent and in violation of 35 U.S.C. § 271(b).

52. Unless enjoined by this Court, Actavis will induce the infringement of the '033 patent by actively and intentionally encouraging, through its label, the infringing use of Actavis's ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Tris's rights under the '033 patent and in violation of 35 U.S.C. § 271(b).

53. Unless enjoined by this Court, Actavis will contribute to the infringement of the '033 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of Actavis's ANDA Product or equipment for the manufacture of Actavis's ANDA Product to others, including manufacturers and distributors, where such materials and apparatuses are not staple articles or commodities of commerce suitable for non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of Actavis's ANDA Product in contravention of Tris's rights under the '033 patent in violation of 35 U.S.C. § 271(c).

54. Tris will be substantially and irreparably damaged and harmed if Actavis's infringement of the '033 patent is not enjoined.

55. Tris does not have an adequate remedy at law for Actavis's infringement of the '033 patent.

56. In the September 3 Notice letter, Actavis has presented no reasonable or good faith position that the '033 patent claims are invalid.

57. This case is an exceptional one, and Tris is entitled to an award of reasonable attorney's fees under 35 U.S.C. § 285.

THIRD CLAIM FOR RELIEF: '390 PATENT

58. Tris realleges paragraphs 1-57 above as if set forth specifically here.

59. The '390 patent (copy attached as Exhibit C), entitled "Orally Effective Methylphenidate Extended Release Powder And Aqueous Suspension Product," was issued on July 15, 2014 to Tris, upon assignment from the inventors Ketan Mehta, Yu-Hsing Tu and Ashok Perumal. The '390 patent claims, *inter alia*, a methylphenidate aqueous extended release oral suspension, and methods of treatment of a patient with such a suspension.

60. Plaintiff Tris has been and still is the owner of the '390 patent. The '390 patent will expire on February 15, 2031.

61. In the September 3 Notice Letter, Actavis FL notified Tris that its ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the '390 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '390 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid,

unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

62. On information and belief, at the time the September 3 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 61 above.

63. Defendants acknowledged and represented that the September 3 Notice Letter meets the statutory and regulatory requirements referred to in paragraph 61, above.

64. The September 3 Notice Letter alleges that Actavis's ANDA Product does not infringe claims 2, 5-7 and 13 of the '390 Patent. Actavis alleges that it does not infringe claim 2 of the '390 Patent because Actavis's ANDA Product "does not exhibit a T_{max} of about 5 hours when administered in a single 60 mg dose to healthy adults." Actavis also alleges that it does not infringe claims 5-7 of the '390 patent because Actavis's ANDA Product "does not contain polyvinylacetate, triacetin or sodium lauryl sulfate." Actavis also alleges that it does not infringe claim 13 of the '390 patent because Actavis's ANDA Product "does not contain a poly (ethyl acrylate-co-methyl methacrylate-co-trimethylammonoethyl methacrylate chloride)."

65. The September 3 Notice Letter provides no other explanation or allegation why Actavis's ANDA Product does not infringe any claim of the '390 patent.

66. Actavis failed to address claims 1, 3, 4, 8-12 and 14-30 of the '390 patent as required by statute and regulation (see paragraph 61, above), thus acknowledging that its ANDA Product meets the all the limitations of these claims.

67. Actavis infringed one or more of the '390 patent claims under 35 U.S.C. § 271(e)(2) by filing its ANDA and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent prior to the expiration of the '390 patent.

68. Unless enjoined by this Court, Actavis will directly infringe the '390 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Actavis's ANDA Product in the United States in violation of 35 U.S.C. §§ 271(a).

69. Unless enjoined by this Court, Actavis will induce the infringement of the '390 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Actavis's ANDA Product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Tris's rights under the '390 patent and in violation of 35 U.S.C. § 271(b).

70. Unless enjoined by this Court, Actavis will induce the infringement of the '390 patent by actively and intentionally encouraging, through its label, the infringing use of Actavis's ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Tris's rights under the '390 patent and in violation of 35 U.S.C. § 271(b).

71. Unless enjoined by this Court, Actavis will contribute to the infringement of the '390 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of Actavis's ANDA Product or equipment for the manufacture of Actavis's ANDA Product to others, including manufacturers and distributors, where such materials and apparatuses are not staple articles or commodities of commerce suitable for non-infringing use,

and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of Actavis's ANDA Product in contravention of Tris's rights under the '390 patent in violation of 35 U.S.C. § 271(c).

72. Tris will be substantially and irreparably damaged and harmed if Actavis's infringement of the '390 patent is not enjoined.

73. Tris does not have an adequate remedy at law for Actavis's infringement of the '390 patent.

74. In the September 3 Notice Letter, Actavis has presented no reasonable or good faith position that the '390 patent claims are invalid.

75. This case is an exceptional one, and Tris is entitled to an award of reasonable attorney's fees under 35 U.S.C. § 285.

WHEREFORE, Plaintiff respectfully requests the following relief:

(a) A judgment be entered that Actavis has infringed the '765 patent, the '033 patent, and the '390 patent by submitting ANDA 206049 to the FDA;

(b) A judgment be entered declaring that the effective date of any approval of Actavis's ANDA 206049 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for the drug product "Methylphenidate HCl Extended Release Oral Suspension, CII" must be later than February 15, 2031, the expiration date of the patents in suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(c) A declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of Actavis's ANDA Product will directly infringe, induce and/or contribute to infringement of the '765 patent, the '033 patent, and the '390 patent;

(d) Preliminary and permanent injunctions be granted enjoining Actavis and its officers, agents, attorneys, and employees, and those acting in privity or concert with them from making, using, selling, offering to sell, or importing Actavis's ANDA Product until after the expiration of the '765 patent, the '033 patent, the '390 patent, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(e) A permanent injunction be granted pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Actavis, its officers, agents, attorneys, and employees, and those acting in privity or concert with them from practicing any composition or method claimed in the '765 patent, the '033 patent, or the '390 patent, or from actively inducing or contributing to the infringement of the '765 patent, the '033 patent, and the '390 patent, until after the expiration of, respectively, the '765 patent, the '033 patent, and the '390 patent, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(f) An award of damages be granted if Actavis engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Actavis's ANDA Product prior to the expiration of the '765 patent, the '033 patent, or the '390 patent, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(g) A judgment be entered declaring that the '765 patent, the '033 patent, and the '390 patent remain valid, remain enforceable and have been infringed by Actavis;

(h) A judgment be entered that Actavis's defenses and claims for relief with respect to the '765 patent, the '033 patent and the '390 patent are limited to those presented in the September 3 Notice Letter;

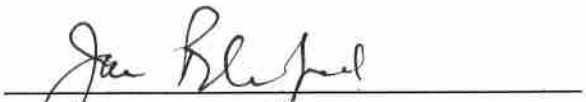
(i) A judgment be entered that Actavis's conduct is exceptional;

(j) An award of attorneys' fees be granted pursuant to 35 U.S.C. § 285;

(k) An award of costs and expenses be granted in this action; and

(l) Such other relief as this Court may deem proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



Jack B. Blumenfeld (#1014)
Regina Murphy (#5648)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
rmurphy@mnat.com

Attorneys for Plaintiff

OF COUNSEL:

Errol B. Taylor
Fredrick M. Zullow
Anna Brook
MILBANK, TWEED, HADLEY & MCCLOY LLP
1 Chase Manhattan Plaza
New York, NY 10005-1413
(212) 530-5000

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